



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,584	06/19/2003	Robert W. Blakesley	55670DIV(45858)	5497
21874 7590 05/01/2007 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205			EXAMINER BRUSCA, JOHN S	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 05/01/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/600,584	<b>Applicant(s)</b> BLAKESLEY ET AL.	
	<b>Examiner</b> John S. Brusca	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2006 and 12 April 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 26,27 and 29-44 is/are pending in the application.
- 4a) Of the above claim(s) 29-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26,27,33-39,43 and 44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/28/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. A power of attorney naming customer number 21874 was entered into the instant application on 31 July 2006.

#### ***Election/Restrictions***

2. This application contains claims 29-32 drawn to an invention nonelected with traverse in the reply filed on 14 March 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

#### ***Drawings***

3. The applicants filed drawings at the time of filing on 19 June 2003 and a second set of drawings on 17 November 2003. The black and white drawings filed on 17 November 2003 are acceptable. On 17 November 2003 an artifact file was created in the application file. This artifact file has been located and examined. The artifact file does not contain color drawings, contrary to the speculation in the Office action mailed 31 May 2006. No further action by the applicants regarding the drawings is required.

#### ***Specification***

4. The substitute specification filed 14 February 2007 has been entered. The applicants are requested to refrain from filing a claim set with substitute specifications to avoid confusion regarding which claim set is the current version.

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1631

6. Claims 40-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 40-42 depend from cancelled claim 28 and are indefinite for being incomplete.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 26, 27, 33-39, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers et al. (cited in the Information Disclosure Statement filed 17 November 2003) in view of Burgoyne (U.S. Patent No. 5,496,562 cited as reference AB in the Information Disclosure Statement filed 17 November 2003) in view of Kahn et al.

The claims are drawn to a method of isolation of vectors from host cells by contacting the host cells with a solid medium. In some embodiments the solid medium protects the vector from

Art Unit: 1631

degradation, is made of cellulose or a micromesh plastic, the host cells are in solution, and the solid medium comprises urate salt, a chelating agent, and an anionic detergent.

Rogers et al. shows in the abstract and throughout recovery of DNA from bacterial liquid cultures by application of the bacterial culture to FTA blood storage medium. Figures 1 and 2 show positive results of PCR assay of bacterial DNA from FTA media to which bacterial cultures were applied. Rogers et al. shows that the DNA is stable for at least 1.6 years after application to the FTA media on page 226. Rogers et al. does not show use of bacteria comprising vectors, media comprising micromesh plastic, and Rogers et al. does not detail the composition of the chemicals in the FTA media. Rogers et al. states on page 223 that FTA medium is described in Burgoyne (U.S. Patent No. 5,496,562).

Burgoyne shows the components of a solid medium for preserving DNA in columns 2-4, including use of a solid support such as cellulose or a micromesh of a synthetic plastic (column 2, lines 21-23), urate, an anionic detergent, and a chelating agent (column 2, lines 54-64 and column 3, lines 18-26). Burgoyne shows the application and storage of isolated plasmids on the solid medium in Example 2, columns 4-6. Burgoyne discloses application of plasmid pUC19 and recovery of approximately 100% of the applied plasmid from the solid matrix in column 6. Burgoyne claims a method of application of generic DNA and recovery of the applied DNA from a solid matrix in at least claim 6.

Kahn et al. reviews plasmid cloning vectors, and shows that such vectors are replicated in bacteria in the abstract and throughout. Kahn et al. shows on page 268 that plasmid vectors are useful for cloning and maintenance of foreign DNA.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Rogers et al. by use of bacteria comprising vectors because Burgoyne shows that the solid media used by Rogers et al. can be used for long term storage and recovery of plasmids, and Kahn et al. shows that bacterial plasmid vectors are useful for cloning and maintenance of foreign DNA.

***Response to Arguments***

10. Applicant's arguments filed 28 November 2006 have been fully considered but they are not persuasive.

The applicants state that Rogers et al. shows isolation of chromosomal DNA but not plasmids from bacteria, and that Burgoyne shows application and recovery of isolated plasmid DNA rather than intact cells comprising plasmid DNA.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The motivation to combine the references, as noted above, is to allow for storage of plasmids present in cells.

The applicants further state that one of ordinary skill in the art would not combine Rogers et al. with Burgoyne because it could not be assumed that plasmid DNA would behave in the same manner as chromosomal DNA in the instant claimed method. The applicants note that Old et al. shows that chromosomal DNA and plasmid DNA have different properties that are taken advantage of in purification protocols. However the purification protocols noted in Old et al. are entirely different than the instant claimed purification protocols. The protocols noted in Old et al.

Art Unit: 1631

use differences in properties between chromosomal DNA and plasmid DNA with regard to density in the presence of ethidium bromide, or denaturation at pH12.0-12.5. Because the instant claimed purification protocol does not rely on these properties, Old et al. does not provide evidence that plasmid DNA would behave differently than chromosomal DNA in the instant claimed method. The applicants state that Hansen et al. (post filing art authored by one of the instant applicants) shows that only low amounts of plasmid DNA remain on the solid matrix when cells comprising plasmids are applied to the matrix. However, Hansen et al. disclose the claimed method and further show on page 74 that sufficient amounts of plasmid DNA are present on the solid matrix to allow for recovery for use in amplification of plasmid DNA sequences of interest, or transformation of recipient cells with the plasmid DNA. Presumably the applicants do not intend to argue that the claimed method is not enabled. The results of Hansen et al. establish that plasmid DNA can be used in the method of Rogers et al. in view of Burgoyne in view of Kahn et al. as noted in the rejection above.

### ***Conclusion***

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

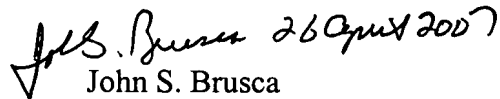
Art Unit: 1631

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
John S. Brusca  
Primary Examiner  
Art Unit 1631

jsb